

Response Under 37 C.F.R. § 41.37
Appellant's Brief
Application No. 08/928,272
Paper Dated: November 22, 2010
In Reply to USPTO Correspondence of May 7, 2010
Attorney Docket No. 3896-092985 (P-3818)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No. : 08/928,272 Confirmation No.: 9434
Applicant : Michael J. ISKRA
Filed : September 12, 1997
Title : **COLLECTION CONTAINER ASSEMBLY**
Group Art Unit : 3771
Examiner : Kristen Clarette Matter

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Appellant appeals the rejections as set forth in the final Office Action mailed on May 7, 2010. This Appeal Brief is submitted in furtherance to the Notice of Appeal electronically filed on August 2, 2010. The Notice of Appeal appeals the final rejection of claims 1 and 5-9. The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 41.37. A two-month Petition for Extension of Time is submitted herewith, along with the requisite fee.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on November 22, 2010.

11/22/2010 Sharyn Beck
Date Signature

Sharyn Beck
Typed Name of Person Signing Certificate

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I. REAL PARTY IN INTEREST

Becton, Dickinson and Company, having its principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417, is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

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II. RELATED APPEALS AND INTERFERENCES

This application (U.S. Patent App. Serial No. 08/928,272) was previously before the Board of Patent Appeals and Interferences in Appeal No. 2005-2410. A Decision on Appeal affirming the Examiner's rejections under 35 U.S.C. §§ 102(b) and 103(a) of the then-pending claims was mailed on September 19, 2005. A copy of this Decision is attached hereto.

There are no other appeals or interferences known to the Appellant, the Appellant's legal representative, or the Assignee of the above-identified application which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

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III. STATUS OF THE CLAIMS

Claims 1 and 5-9 are pending in the present application and are the subject of this Appeal. Claim 1 is in independent form. Claims 1 and 5-9 stand finally rejected under 35 U.S.C. § 103(a) for obviousness based on United States Patent No. 5,458,854 to Burns (hereinafter “the Burns patent” or “Burns”) in view of United States Patent No. 3,918,909 to Arlman (hereinafter “the Arlman patent” or “Arlman”). All other claims have been cancelled and are not part of this Appeal.

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IV. STATUS OF AMENDMENTS

All amendments previously made to the claims have been entered. The claims have not been amended after being finally rejected. A copy of the claims, as presently pending, is provided in the Claims Appendix attached hereto.

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V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a one piece collection container assembly (50). (*See* Figs. 3 and 4.) The assembly (50) includes an elongate tubular housing having a sidewall (62) extending between opposed first and second ends. (*See* Figs. 3 and 4; *see also* page 4, lines 12-14 and page 8, lines 13-22.) The assembly (50) further includes a solid partition (76) in contact with the sidewall (62). (*See* FIGS. 3 and 4; *see also* page 9, lines 3-5.) The solid partition (76) is positioned within the housing between the first end and the second end. (*Id.*) The solid partition (76) forms a closed bottom. (*See* FIGS. 3 and 4; *see also* page 4, lines 14-25 and page 8, line 17 through page 9, line 6.) The housing defines a volume for specimen collection and containment therein between the first end and the partition. (*See* Figs. 3 and 4; *see also* page 4, lines 12-14 and page 8, line 24 through page 9, line 5.) The second end forms a false bottom which includes a bottom end that is below the partition. (*See* FIGS. 3 and 4; *see also* page 4, lines 14-19 and page 8, lines 19-22.) The bottom end has an annular skirt (78) and a semi-spherical bottom (80) which has an opening (82) therein. (*See* Figs. 3 and 4; *see also* page 4, lines 12-14 and page 8, lines 19-22.)

Other than claim 1, there are no other independent claims involved in this Appeal.

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VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Based upon the rejections presented in the final Office Action dated May 7, 2010, Appellant presents the ground of rejection to be reviewed on Appeal:

I. . . Whether claims 1 and 5-9 were properly rejected under 35 U.S.C. § 103(a) for obviousness based upon the Burns patent in view of the Arlman patent.

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VII. ARGUMENT

All of the presently pending claims were improperly rejected in the final Office Action. In general, the final Office Action fails to demonstrate that the combination of the Burns patent and the Arlman patent would suggest to one skilled in the art a one-piece collection container assembly comprising a solid partition positioned between the first and second ends of a tubular housing where the second end of the housing forms a false bottom with a bottom end comprising an annular skirt and a semi-spherical bottom with an opening therein.

For at least this reason, which is discussed in greater detail hereinafter, Appellant respectfully requests that the Board overturn the rejection of the Examiner, and remand this matter to the Examiner with instructions to reopen prosecution.

I. CLAIMS 1 AND 5-9 WERE IMPROPERLY REJECTED UNDER 35 U.S.C. 103(a) FOR OBVIOUSNESS BASED ON BURNS AND ARLMAN

Claims 1 and 5-9 stand finally rejected under 35 U.S.C. § 103(a) for obviousness based on the Burns patent and the Arlman patent. In view of the following remarks, Appellant respectfully requests reversal of this rejection.

A. The Scope and Content of the Prior Art

1. The Burns Patent

The Burns patent is directed to a collection assembly (10) comprising a container (12) and a cap (14). The container (12) has a sidewall (22) that extends from an upper portion (28), which includes an open end (31), to a lower portion (30), which includes a closed bottom end (38) and an annular skirt (37) extending from the closed bottom end. The cap (14) has an annular outer skirt (58) and an inner annular inverted recessed skirt portion (64). The annular skirt (37) of the collection assembly (10) "provides a means for allowing the container to be placed on a flat surface." (Burns, col. 3, lines 52-53.) Particularly, "[w]hen the cap is positioned on the bottom of the container during fluid collection, the cap provides a means for allowing the container to be placed upright on a flat surface." (Burns, col. 5, lines 9-12; *see also* FIG. 6.) The collection assembly in Burns is for use in collecting small quantities of blood in a secure fashion

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for subsequent testing. (Burns, col. 1, lines 10-14.) The collection assembly is purported to be particularly useful in micro-centrifuges. (Burns, col. 2, lines 43-44.) The disclosed advantages of the Burns collection assembly include, *inter alia*, that radial spray of excess fluid is minimized, that the cap can be secured and unsecured to the annular space in the skirt at the bottom of the cap, and that the rim of the cap can substantially prevent contamination to the specimen inside the container when the cap is secured to the container. (Burns, col. 2, line 49 through col. 3, line 7.)

2. The Arlman Patent

The Arlman patent is directed to an apparatus used in saturation determinations. (Arlman, Abstract.) Such saturation determinations are made by mixing a quantity of a chemical or biological substance in the presence of a binder with a known quantity of the same substance which is radioactively labeled, reacting the various compounds, and then separating the bound radioactive substance from the unbound form. (Arlman, col. 1, lines 5-34.) The apparatus for performing this analysis discussed in Arlman includes a tubular member (1) open at both ends with a hollow cylindrical downward projection (2) at the lower end in which a porous plug has been inserted. (Arlman, col. 4, lines 40-44.) The tubular member is split by a permeable membrane (16) into a reaction compartment (10), which is located at the upper part of the tubular member, and a separating compartment, located at the lower part. (Arlman, col. 4, lines 40-60.) A sample can be introduced into the reaction compartment by removing the cover (11) or puncturing the cover (11) with a sharp object. (Arlman, col. 3, lines 12-18.) The separating compartment includes the separating agent (8). (Arlman, col. 4, lines 45-46.) Once an equilibrium between the reactants is established in the reaction compartment, the cap (7) disposed on the cylindrical downward projection (2) is removed and a glass rod is used to pierce the membrane (16) separating the reaction compartment from the separation compartment. (Arlman, col. 5, lines 21-28.) The contents of the reaction compartment then flow under the influence of gravity into the separation compartment and contact the separation agent. (Arlman, col. 5, lines 28-31.) Washing liquid is then introduced through the reaction compartment and discharged through the opening in the downward projection (2). (Arlman, col. 5, lines 34-39.)

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Arlman proffers that this apparatus overcomes the disadvantages of the prior art by providing a container which is closed with respect to the separating agent and having a wall that is liquid permeable separating the reaction container. (Arlman, col. 2, lines 41-61).

B. The Burns Patent is Recognizably Distinguishable from Claim 1

Independent claim 1 defines a one piece collection container assembly comprising an elongate tubular housing. With respect to the elongate tubular housing, claim 1 recites, in relevant part, “said second end [of the elongate tubular housing] forming a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein.” (emphasis added).

The Examiner asserts that Burns discloses a one piece collection container assembly having an elongate tubular housing (12) having opposed first and second ends (as shown in Fig. 2), a solid partition (38) contacting a sidewall (22) of the tube forming a closed bottom (38) and positioned within said housing between the first and second ends (as shown in Fig. 2). The Examiner further contends that the housing defines a volume for specimen collection and containment therein between the first end and said partition, the second end forming a false bottom having a bottom end below the partition having an annular skirt (37) having an opening (47) therein. The Examiner recognizes, however, that Burns does not disclose that the bottom of the tube is semi-spherical. This recognized deficiency in Burns is confirmed by reference to, for instance, Figures 1, 2, 5 and 6 of Burns, each of which shows a container having a flat bottom edge (47) formed from the annular skirt (37) which provides a means for allowing the container to be placed upright on a flat surface. (Burns, col. 3, lines 48-53.)

Thus, there exists a clear and recognized difference between the claimed design and the design disclosed in Burns. Specifically, where the container in the Burns patent has a flat bottom edge, the bottom end of the claimed collection container comprises a semi-spherical bottom with an opening therein.

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C. It Would Not be Obvious to Modify Burns in view of Arlman

Despite the recognized differences between what is taught in Burns and what is defined in claim 1, the Examiner concluded that the claims do not define over the prior art. In particular, the Examiner asserted that it would have been obvious, in view of Arlman, to modify Burns to include a bottom edge that is semi-spherical. However, the rationale provided to support this conclusion is insufficient to establish a *prima facie* case of obviousness and inconsistent with the actual teachings of the cited art. Moreover, Burns and Arlman are not analogous art, and thus would not have been combined in the first place. Therefore, the rejection under 35 U.S.C. 103(a) is improper and should be withdrawn.

1. Burns and Arlman are Non-Analogous Art

In rejecting claims 1 and 5-9, the Examiner asserted that one skilled in the art would find it obvious to modify the shape of the container bottom in Burns to be semi-spherical in view of the Arlman patent. However, the conclusion that one skilled in the art would look to Arlman in the first place is based on the erroneous observation that "Arlman teaches a specimen collection tube...." (Final Office Action, page 3.) Instead, as described above, Arlman is directed to an entirely unrelated type of container, namely one having separate reaction and separation compartments divided by a permeable membrane that is used in performing saturation analyses. Thus, in addition to the fact that Arlman provides no teaching to modify Burns in the manner proposed in the Office Action (discussed *infra*), one skilled in the art would not look to the Arlman patent to begin with because Arlman is a non-analogous reference.

To rely on a reference under 35 U.S.C. 103(a), the reference must be analogous art. The analogous art inquiry is meant to defend against improper hindsight reconstruction of the claims by first asking whether one skilled in the art would even look to the teachings of the cited reference in making the allegedly obvious combination. *In re Kahn*, 441 F.3d 977, 987, 78 USPQ.2d 1329, 1336 (Fed. Cir. 2006). As set forth in *Kahn*, this "requires that the Board show that a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for

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rejection." *In re Kahn*, 78 USPQ.2d at 1335-36. Section 2141.01(a) of the MPEP, promulgated after the decision in *KSR*, further confirmed that a reference, to be considered analogous art, must be in the field of applicant's endeavor or otherwise deal with a problem similar to that being addressed by the applicant. In particular, Section 2141.01(a) states:

The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." *KSR International Co. v. Teleflex Inc.* ... 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

Following the above analytical guidelines, it is clear that the Arlman patent is non-analogous art with respect to false-bottomed collection containers, the subject of both the Burns patent and the present invention, and should therefore not have been considered by the Examiner.

Both Burns and the present application are concerned with false bottom collection tube assemblies. More particularly, the Burns patent is concerned with the cap portion of the collection tube assembly and the manner in which the cap interacts with both the top of the container to reduce fluid leakage and the bottom of the container to allow the container to be placed in an upright position. Above all, however, the "microcollection" container of the Burns patent is for the collection of "small quantities of blood from a patient and maintaining the blood in a secure fashion for subsequent testing." (Burns, col. 1, lines 10-13.) Similarly, the subject application is directed to a specimen collection container for collecting and storing a small quantity of biological fluid samples. (Specification, page 1, lines 14-18.)

Arlman, on the other hand, is concerned with a container for conducting saturation analyses where the container is open at both ends, has distinct reaction and separation compartments separated by a permeable membrane, and includes a hollow cylindrical downward portion. (*See supra* at 10.) The fields of endeavor of small volume, false bottomed collection

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tubes and saturation determination reaction apparatuses are widely divergent, and there is simply no support for the conclusion that one skilled in the art of collection assemblies useful for collecting small quantities of blood would consider saturation reaction containers such as in Arlman to be relevant or related technology.

The problems confronting the inventor of the subject application would also not provide a basis to conclude that Arlman is analogous art. As set forth in the subject application, the applicant was confronted with a problem that known false bottomed collection tubes were incompatible with standard clinical equipment and instrumentation. (Specification, page 4, lines 4-8.) There is no basis to assume one skilled in the art faced with this problem would look to the Arlman patent. In fact, there is absolutely no suggestion, explicit or otherwise, that the Arlman apparatus, or apparatuses of its kind, interact with clinical equipment or instrumentation at all. In fact, since during the washing step the washing liquid is discharged through projection (2), projection (2) cannot be adapted for engagement with common instrument compatibility for housing the tube.

One of ordinary skill in the art tasked with developing false bottomed collection assemblies that are compatible with common instrumentality would not reasonably look to references that are directed to reaction containers such as those disclosed in Arlman. Accordingly, the Arlman patent is non-analogous art and should not have been considered by the Examiner in formulating the outstanding rejection of claims 1 and 5-9. For this reason alone, the rejection is improper and should be reversed.

2. The Asserted Reasons for Modifying Burns do not Support a Finding of Obvious

The Examiner provides several reasons for concluding that claims 1 and 5-9 are obvious over Burns in view of Arlman. However, these reasons are not supported by any evidence of record and are inconsistent with the actual teachings of the cited art. Therefore, the rejection of claims 1 and 5-9 under 35 U.S.C. 103(a) should be reversed.

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First, in the paragraph bridging pages 2 and 3 of the Office Action, the Examiner asserts that modifying the bottom end of the tube in Burns so that it is semi-spherical is “an obvious design consideration” that does not patentably distinguish over the prior art. However, the Examiner does not offer any explanation as to why this is an obvious design consideration or otherwise expand on this conclusion. The bald conclusion that changing the shape of the Burns design to make it semi-spherical is an “obvious” design consideration simply assumes what it purports to explain. Namely, why, based on evidence of record, it would be obvious to modify the Burns design to include a semi-spherical bottom end. Such unsupported and unreasoned rejections are exactly the type the Federal Circuit and Supreme Court have warned against. See *In re Kahn*, 78 USPQ.2d at 1336 (“rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”); *see also KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 415, 82 USPQ.2d 1385, 1396 (2007) (quoting Federal Circuit statement from *Kahn* with approval). Therefore, this rationale fails to support a *prima facie* case of obviousness.

The Examiner further posits that changing the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube. Again, though, this conclusion is not based on any reasoning or other rationale culled from the cited references or elsewhere. Instead, this reasoning appears to be pulled directly from the specification of the subject application itself. Indeed, the subject specification states that a “further advantage of the assembly of the present invention is that it provides a specimen collection container which is universally compatible with various clinical equipment and instrumentation.” (Specification, page 5, lines 21-26.) Of course, it axiomatic that the obviousness determination cannot be based on knowledge gleaned from applicant’s disclosure but must instead be based on the state of the art at the time the subject application is filed. *In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Thus, this rationale fails as well.

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The Examiner, on page 3 of the final Office Action, also contends that Arlman discloses a specimen collection tube with a false bottom surface having a semi-spherical shape. The Examiner asserts that it would have been obvious to combine the assembly of Burns with the false bottom having a semi-spherical shape of Arlman to allow compatibility with standard clinical equipment because such a shape was well known at the time the invention was made. However, even if Arlman would be considered analogous prior art, which Appellant denies (*see supra* at 12-14), Arlman fails to disclose or suggest a false bottom having a semi-spherical shape, as recited in independent claim 1. Arlman discloses a tubular member (1) having a projection (2) including a cap (7). (See Arlman, col. 4, lines 40-53.) Arlman fails to disclose or suggest not only a false bottom portion, as both projection (2) and reaction compartment (10) form portions of the functional mixing chamber of the device, but also that the bottom of the tube is adapted for common instrument compatibility, as the washing liquid is discharged through projection (2), and thus, projection (2) cannot be adapted for engagement with common instrument compatibility for housing the tube. Thus, Arlman fails to provide the alleged teaching supporting the Examiner's conclusion of obviousness.

Appellant further submits that Burns specifically requires that the bottom end of the tube includes a cylindrical shape for receiving a portion of the cap thereon. As recited in Burns at column 5, lines 7-12, "As shown in Fig. 6, cap 14 is readily compatible with skirt 37 on the lower portion of the container. Space 68 of the cap receives the skirt of the container. *When the cap is positioned on the bottom of the container during fluid collection, the cap provides a means for allowing the container to be placed upright on a flat surface.*" Accordingly, the bottom of the tube of Burns is cylindrical to allow the cap to be engaged therewith to provide a means for allowing the container to be placed on a flat surface during fluid collection. Burns is entirely silent as to: 1) that the bottom end of the tube is semi-spherical; and 2) that the bottom of the tube is adapted for common instrument compatibility. Indeed, modifying the bottom end of the Burns collection tube to include a semi-spherical shape could destroy one of the advantages of the Burns design, namely that the bottom end of the tube can accept the cap portion. The comments by the Examiner on pages 4 and 5 of the Office Action that the Burns tube, as

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modified, could stand upright through the use of a stand ignores the fact that Burns explicitly teaches that one intended purpose of the container design is to allow the container to stand upright on a flat surface, without a need for any such separate stand. As the MPEP reminds us, “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP 2143.01, subpart II (*citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).) The Examiner cannot use the claims as a blueprint for locating separate claim elements in separate prior art references without considering the teachings of the prior art as a whole and without considering the complete teachings of the separate references. *In re Dembiczaik*, 175 F.3d 994, 999 (Fed. Cir. 1999); *See also In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965) (“It is impermissible...to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”). Thus, the proposed modification of Burns fails to consider the Burns patent as a whole, including the teachings away of a container having a semi-spherical bottom.

Thus, neither Burns, nor Arlman, nor the combination of Burns and Arlman, disclose or suggest a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein, as recited by Appellant's claim 1. Appellant further submits that neither Burns nor Arlman provide a motivation or reason for a worker in the art to modify Burns to include a semi-spherical bottom. In fact, Burns expressly teaches away from the inclusion of a semi-spherical bottom for the reasons discussed herein. Therefore, the rejection of claims 1 and 5-9 as obvious over Burns in view of Arlman is improper and should be reversed.

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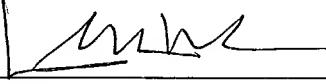
VIII. CONCLUSION

For the reasons set forth above, Appellant submits that claims 1 and 5-9 are indeed patentable over the cited art and are in condition for allowance. Reversal of all of the Examiner's rejections and remand of this case to the Examiner are respectfully requested.

The Commissioner of Patents and Trademarks is hereby authorized to charge the fee of \$540.00 by credit card, which information accompanies this Appeal Brief. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees which may be required to Deposit Account Number 23-0650. Please refund any overpayments to Deposit Account Number 23-0650.

Respectfully submitted,

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CLAIMS APPENDIX

1. A one piece collection container assembly comprising:
 - an elongate tubular housing having a sidewall extending between opposed first and second ends; and
 - a solid partition in contact with said sidewall, positioned within said housing between said first and second ends, forming a closed bottom;
 - said housing defining a volume for specimen collection and containment therein between said first end and said partition;
 - said second end forming a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein.
5. The assembly of Claim 1, wherein said partition is arcuate in shape to provide said volume for specimen collection with at least a partially rounded bottom portion.
6. The assembly of Claim 1, wherein said partition is conical in shape.
7. The assembly of Claim 1, wherein said housing is a thermoplastic polymer.

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8. The assembly of Claim 7, wherein said thermoplastic polymer is polyethylene terephthalate, polypropylene, polyethylene napthalate, polyvinyl chloride or copolymers thereof.

9. The assembly of Claim 1, wherein said housing comprises an outer diameter, a length and an internal volume, wherein said outer diameter is about 13 to about 16 millimeters, said length is about 75 to about 100 millimeters and said internal volume is about 1 to about 3 milliliters.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

1. Copy of the Decision on Appeal of Appeal No. 2005-2410, mailed September 19, 2005, concerning United States Patent Application No. 08/928,272.